

This document is scheduled to be published in the Federal Register on 11/27/2012 and available online at <a href="http://federalregister.gov/a/2012-28727">http://federalregister.gov/a/2012-28727</a>, and on FDsys.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-12GO]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7570 or send an email to <a href="mailto-omb@cdc.gov">omb@cdc.gov</a>. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

## Proposed Project

Colorectal Cancer Control Program Indirect/Non-Medical

Cost Study — New — National Center for Chronic Disease

Prevention and Health Promotion (NCCDPHP), Centers for

Disease Control and Prevention (CDC).

## Background and Brief Description

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening with fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, and/or colonoscopy is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons. In 2009, by applying lessons learned from a four-year e demonstration program, CDC designed and initiated the larger population-based Colorectal Cancer Control Program (CRCCP) at 29 sites with the goals of reducing health disparities in CRC screening, incidence and mortality.

To date there has been no comprehensive assessment of all the costs associated with CRC screening, especially indirect and non-medical costs that may act as barriers to screening, incurred by the low-income population served by the CRCCP. CDC proposes to address this gap by collecting information from a subset of patients enrolled in the program. CDC plans to conduct the information collection in partnership with providers in five states (Alabama, Arizona, Colorado, New York, and Pennsylvania).

Each provider site will administer the survey to patients who undergo screening by FIT or colonoscopy until it reaches a target number of responses. Targets for each site range between 75 and 150 completed questionnaires, depending on the volume of patients screened. Patients who undergo fecal immunochemical testing will be asked to complete the FIT questionnaire, which is estimated to take about 10 minutes. Patients who undergo colonoscopy will be asked to complete the Colonoscopy questionnaire, which includes additional questions about the preparation and recovery associated with this procedure. The estimated burden per response for the Colonoscopy questionnaire is 25 minutes. Demographic information will be collected from all patients who participate in the study. Participation in the study is voluntary, but patients will be offered an incentive in the form of a gift card. Each participating provider will make patient navigators available to assist patients with coordinating the screening process and completing the questionnaires. Providers will be reimbursed for patient navigator time and administrative expense associated with data collection.

This information collection will be used to produce estimates of the personal costs incurred by patients who undergo CRC screening by FIT or colonoscopy, and to improve understanding of these costs as potential barriers to participation. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve delivery of CRC screening services and to increase screening rates among low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

OMB approval is requested for one year. Each respondent will have the option of completing a hardcopy questionnaire (in English or Spanish) or an on-line questionnaire. No identifiable information will be collected by CDC or CDC's data collection contractor. There are no costs to respondents other than their time. The total estimated annualized burden hours are 181.

## Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hr)
Patients Served by the Colorectal Cancer Control Program	FIT Questionnaire	300	1	10/60
	Colonoscopy Questionnaire	315	1	25/60

DATE: November 19, 2012

Ron A. Otten, Ph.D.
Director, Office of Scientific
Integrity (OSI)
Office of the Associate Director for
Science (OADS)
Office of the Director
Centers for Disease Control and
Prevention

[FR Doc. 2012-28727 Filed 11/26/2012 at 8:45 am; Publication Date: 11/27/2012]